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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/516,521

05/02/2005

Jurgen Dolderer

23136

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535 7590 10/10/2007
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EXAMINER

SUTTON, DARRYL C

ART UNIT

PAPER NUMBER

4133

MAIL DATE

DELIVERY MODE

10/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/516,521

Applicant(s)

DOLDERER, JURGEN

Examiner

Darryl C. Sutton

Art Unit

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08/27/2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-13 is/are pending in the application.
- 4a) Of the above claim(s) 8-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 November 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of Group 3 in the reply filed on 8/27/2007 is acknowledged. The traversal is on the ground(s) that the reference use to show lack of unity provides no basis to support that there is no common technical feature. This is not found persuasive because the Wang reference used to show lack of unity does show that the claimed compound (ER-4031) is known in the art. It also discloses that the compound can be used to block or deactivate the HERG potassium channel. HERG potassium channels are known to be expressed in cancer cells, including adenocarcinomas, which account for a vast majority of colorectal cancer cases. One of the applicant's claimed limitations was to treat colorectal cancer that was caused by the presence of HERG potassium channels, by using the compound. If the channels are effectively blocked by the compound, then the colorectal cancer would be treated. Therefore, no special technical feature exists and there is a lack of unity between the groups.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-7 are cancelled, and new claims 8-13 have been submitted. New claims 12 and 13 correspond to the invention originally covered by Group III. The applicant requests that the examiner rejoin Groups II and III. Applicant's arguments for rejoining Groups II and III were not persuasive. The restriction between the groups is

maintained and Group III (new claims 12 and 13) will be examined. Claims 8-11 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Step (c) of the method should include "at least one" between "presence of" and "HERG channel" to be consistent with the proceeding steps. The limitation of "relating" the presence of HERG potassium channel in line 13 of the claim is unclear. Examiner is unsure what the applicant means by relating, and what steps are taken to relate the presence of at least one HERG channel to colorectal carcinoma. Also, if the HERG potassium channel is not detected, then step (c) with the limitation "relating" is not performed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1609

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillman et al. (U.S. Patent No. 6,071,720 in view of Bianchi et al. (Cancer Res., 1998) and further in view of Wang et al. (FEBS, 1997), already noted in restriction requirement and on the record.

The claims are drawn to a method of treatment of colorectal carcinoma by administering a therapeutically effective amount of 4-[1-{2-(6-methyl-2-pyridinyl) ethyl-4-piperidinyl} carbonyl] methane-sulfoanilide 2HCl.

Hillman et al. teaches that HERG potassium channel subunits mediate rectifying delayed-type potassium current (see column 2, lines 7-14); and that a new delayed rectifier potassium channel (DRPCS) subunit was discovered which provides new treatments of cancers (column 2, lines 55-60). Hillman et al. also teaches that an antagonist of the delayed potassium rectifier subunit is administered to treat cancer, including adenocarcinoma, and particularly cancers of the gastrointestinal tract, i.e. colorectal cancer (column 19, lines 12-25).

Hillman et al. does not teach that blocking HERG potassium channels with 4-[1-{2-(6-methyl-2-pyridinyl) ethyl-4-piperidinyl} carbonyl] methane-sulfoanilide 2HCl would treat colorectal cancers.

Bianchi et al. teaches that adenocarcinoma cells possess a rectifier current which is biophysically and pharmacologically similar to the HERG potassium current (page 815, Abstract). Bianchi also teaches that HERG is highly conserved in tumor lines (page 819, Discussion); and that HERG channels are not only operative in the heart but play a role in tumor cells of various lineages (page 820, 2nd column, 2nd paragraph).

Wang et al. teaches that E-4031 or 4-[1-{2-(6-methyl-2-pyridinyl) ethyl-4-piperidinyl} carbonyl] methane-sulfoanilide 2HCl inhibits or blocks delay rectifier potassium current (Abstract, and page 43, 1st paragraph), i.e. acts as a antagonist of the HERG potassium channel subunit.

At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the treatment of Hillman et al. to include the antagonist or inhibitor of Wang et al., since both the HERG of Wang et al. and the DRPCS of Hillman et al. both function to mediate rectifying delay-type potassium current, and therefore affect cancer cells in the same way; and inhibiting the rectifying delay-type potassium current is a way to treat cancer. Obtaining biopsy of cancerous tissue, lymph nodes, or samples of bodily fluids such as stool to perform assays to detect biomarkers of cancer is well known in the art. It would have been obvious to perform those steps for any biomarker of the disease in a method for treating cancer.

All claims are rejected.


Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 8:00AM to 4:45pm or Fr from 8:00AM to 3:45PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached on M-Th from 8:00AM to 4:00PM at (571)272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

DCS


JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER